REMARKS

Claims 1-10 were previously pending in this application. Claims 1- 4 and 6 have been amended, non-elected claim 5 has been cancelled without prejudice to or disclaimer of the underlying subject matter, and new claims 11-15 have been added. Support for the new and amended claims can be found throughout the specification, for example, at page 6, line 33 through page 7, line 15, in the sequence listing, and in the claims as originally filed. The specification has been amended at the request of the Examiner to remove hyperlinks and browser executable code and to correct typographical errors. No new matter enters by way of these amendments.

1. Restriction/Election

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claim from the application.

Applicants further acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 1, February

2003, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 2.

2. Specification – Browser Executable Code

The specification has been objected to for purportedly containing "embedded hyperlink and/or other form of browser-executable code." Office Action at page 2. In addition, the specification has been objected to for the inclusion of two tandem commas. *Id.*

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that on the United States Patent and Trademark Office website, one cannot click on the hyperlink and be transported to another, potentially commercial, website. This requirement does not exclude the listing of a website that is not present as a hyperlink.

Applicants respectfully note that no hyperlinks were found on the page cited by the Examiner in the Office Action. However, Applicants have reviewed the specification and have amended the specification to remove the phrase "http://www" and embedded hyperlinks (instead listing the websites using the format "available on the worldwide web

at websitename.html"). The citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

Applicants also respectfully note that tandem commas were not found on the page cited by the Examiner in the Office Action. However, Applicants reviewed the specification and identified tandem commas on page 49, line 5. Applicants have amended the paragraph beginning on page 48, line 30 to remove the second of the tandem commas.

In light of these amendments, applicants respectfully request withdrawal of the objection to the specification.

3. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1-4 and 6-10 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 3.

Claim 1 is allegedly indefinite in the recitation of the phrase "degenerate variant" because "the application does not define the term variant in this context." Office Action at page 3. Applicants respectfully disagree, however, in order to facilitate prosecution, claim 1 has been amended to delete the phrase "degenerate variant." As such, Applicants respectfully request that the Examiner withdraw this indefiniteness rejection.

Claims 1, 4 and 6 are allegedly indefinite "because they are broader that [sic] the elected invention in that they recite more SEQ ID NOs than the one elected." Office Action at page 3. Claims 1, 4 and 6 have been amended to claim the subject matter elected in the Response to Restriction Requirement filed on April 3, 2003. In view of

these amendments, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

Claim 2 is allegedly indefinite in the recitation of the phrase "fragment thereof" because "no lower limit for the fragment size is recited." Office Action at page 3. Applicants respectfully disagree, however, in order to facilitate prosecution, claim 1 has been amended to delete the phrase "or fragment thereof." Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

Claim 3 is allegedly incomplete "because there is no provision for the claim to refer to a table in the specification." Office Action at page 3. In addition, Claim 3 is allegedly incomplete "because it makes an improper incorporation by reference to material that is not in and [sic] issued U.S. Patent or allowed U.S. Patent application." *Id.* Claim 3 has been amended to recite the material referred to in Table 1. As such, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

4. Claim Rejections – 35 U.S.C. § 101

Claims 1-4 and 6-10 have been rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. Office Action pages 3-4. In particular, the Examiner alleges that the specification "does not disclose a specific, substantial, and credible utility for SEQ ID NO: 2 or for any polypeptide that is encoded by SEQ ID NO: 2." *Id.* at page 4. Applicants respectfully disagree with the Examiner.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The instant specification

discloses many utilities that satisfy this requirement. One such utility is the use of the claimed nucleic acid molecule in detecting the presence, absence or level of an organism in a sample. Specification at page 52, lines 24-26. Another one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 53, line 7 through page 58, line 19. Further uses of the claimed nucleic acid molecules are provided for at page 51, *et. seq.*, under the heading "Uses of the Agents of the Present Invention." Many of these utilities, including the utilities argued above, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. The Examiner ignores the disclosed utilities, and simply argues that the claimed invention lacks patentable utility, but does not provide **any** support (legal or factual) for the proposition that these utilities are not legal utilities.

The Examiner has not provided **any** evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [he] must set forth factual reasons which would lead one skilled in the art to question the objective

truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Thus, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the

specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-4 and 6-10 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 1-4 and 6-10 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.,* an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

6. Claim Rejections – 35 U.S.C. § 102(b)

Claims 2 and 3 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Couture *et al.* (Mol. Gen. Genet. 243 (2), 185 (1994)) ("Couture, *et al.*"). Although Applicants disagree with this rejection, to facilitate prosecution, claims 2 and 3 have been amended to delete the phrase "or fragment thereof."

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). In the present application, amended claims 2 and 3 are directed to isolated nucleic acid molecules comprising SEQ ID NO: 2 that encode a *Chlorella sarokiniana* protein. Whatever else Couture *et al.* teaches, it does not disclose SEQ ID NO: 2 in its entirety. Absent a teaching of each and every element of the claim, *i.e.*, SEQ ID NO: 2, the reference cited by the Examiner does not anticipate claims 2 or 3 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 2 and 3 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at (202) 942-5085 should any additional information be necessary for allowance.

Respectfully submitted,

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